

# **INFORMATION DISCLOSURE STATEMENT BY APPLICANT** ( Not for submission under 37 CFR 1.99)

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| Application Number     | 12588082     |
| Filing Date            | 2007-06-20   |
| First Named Inventor   | Jens Fogh    |
| Art Unit               | 1652         |
| Examiner Name          | Yong D. Pak  |
| Attorney Docket Number | S2071-7038US |

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|                    | 4       | William R. PEARSON et al., "Improved tools for biological sequence comparison", Proc Natl Acad Sci USA, Vol 85, pp 2444-2448, April 1988.   | <input type="checkbox"/> |

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|----|--|--------------------------|
| 5  | William R. PEARSON, "(5) Rapid and Sensitive Sequence Comparison with FASTP and FASTA", METHODS OF ENZYMOLOGY, vol. 183, 1990, pp. 63-98.  | <input type="checkbox"/> |
| 6  | Julie D. THOMPSON et al., CIUSTAI W: improving the sensitivity of progressive multiple sequence alignment through sequence weighting, position-specific gap penalties and weight matrix choice", Nucleic Acids Research, 1994, vol. 22, no. 22, 4673-4680. | <input type="checkbox"/> |
| 7  | Arvan I. FLUHARTY et al., "[58] Arylsulfatases A and B from Human liver", Meth. Enzymol. 50:537-547, 1978.   | <input type="checkbox"/> |
| 8  | Abdul WAHEED et al., "Phosphorylation and sulfation of arylsulfatase A accompanies biosynthesis of the enzyme in normal and carcinoma cell lines", Biochimica et Biophysica Acta 847 (1985) 53-61.   | <input type="checkbox"/> |
| 9  | Thomas BRAULKE et al., "SULFATED OLIGOSACCHARIDES IN HUMAN LYSOSOMAL ENZYMES", BIOCHEMICAL AND BIOPHYSICAL RESEARCH COMMUNICATIONS, vol. 143, no. 1, 1987, pp. 178-185.  | <input type="checkbox"/> |
| 10 | Thomas BRAULKE et al., "Insulin-like Growth Factors I and II Stimulate Endocytosis but Do Not Affect Sorting of Lysosomal Enzymes in Human Fibroblasts", The Journal of Biological Chemistry, Vol. 265, No. 12, Issue of April 25, 1990, pp. 6650-6655.    | <input type="checkbox"/> |
| 11 | Bernadette M. KELLY et al., "Presence of a lysosomal enzyme, arylsulfatase-A, in the prelysosome-endosome compartments of human cultured fibroblasts", European Journal of Cell Biology, 48, 71-78, 1989.  | <input type="checkbox"/> |
| 12 | Nathan N. ARONSON, JR et al., "Lysosomal degradation of Asn-linked glycoprotein", the FASEB Journal, Vol. 3, Dec 1989, pp. 2615-2622.  | <input type="checkbox"/> |
| 13 | Oivind NILSSEN et al., "a-Mannosidosis: functional cloning of the lysosomal a-mannosidase cDNA and identification of a mutation in two affected siblings", Human Molecular Genetics, 1997, Vol 6 No 5, pp. 717-726.  | <input type="checkbox"/> |
| 14 | Yasufumi KANEDA et al., "Regional assignment of five genes on human chromosome 19", CHROMOSOMA (BerJ) (1987) 95:8-12.  | <input type="checkbox"/> |
| 15 | Hilde Monica Frostad RIISE et al., "Genomic Structure of the Human Lysosomal a-Mannosidase Gene (MANB) GENOMICS 42, 200-207 (1997).  | <input type="checkbox"/> |

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| 16 | Yung-Feng LIAO et al., "Cloning, Expression, Purification and Characterization of the Human Broad Specificity Lysosomal Acid a-Mannosidase", The Journal of Biological Chemistry, Vol. 271, No. 45, Issue of November 8, 1996, pp. 28348-28358. | <input type="checkbox"/> |
| 17 | Vicki L. NEBES et al., "HUMAN LYSOSOMAL ALPHA-MANNOSIDASE: ISOLATION AND NUCLEOTIDE SEQUENCE OF THE FULL-LENGTH cDNA", BIOCHEMICAL AND BIOPHYSICAL RESEARCH COMMUNICATIONS, Vol. 200, No.1, 1994, pp. 239-245.                                  | <input type="checkbox"/> |
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| 20 | Peter MEISSNER et al., "Allosteric Inhibition of Human Lymphoblast and Purified Porphobilinogen Deaminase by Protoporphyrinogen and Coproporphyrinogen", J. Clin. Invest., 1993, vol. 91,1436-1444.   | <input type="checkbox"/> |
| 21 | James AUSTIN et al., "Abnormal Sulphatase Activities in Two Human Diseases (Metachromatic Leucodystrophy and Gargoylism)", Biochem. J. (1964),93, 15c-17c.  | <input type="checkbox"/> |

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